

REMARKS

Claims 1-25 are pending in the instant application. Claim 1 is amended to more particularly point out and distinctly claim Applicant's invention. Specifically, claim 1 is amended to recite that "the wound" is a "surgically closed wound." Support for this amendment is found in the specification as filed, *inter alia*, at page 4, lines 13-22.

THE REJECTION UNDER 35 U.S.C. § 102 OVER KELLY SHOULD BE WITHDRAWN

Claims 1-4 and 10 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kelly (1996) *Br. J. Obstet Gynaecol* 103:837-839 ("Kelly"). More specifically, with respect to Kelly, the Examiner has alleged at page 4 of the Office Action that:

Kelly (1996) teaches a method of a method of ceasing pain after laparoscopic procedure using a direct application of bupivacaine into fallopian tubes, see 1st paragraph at page 837. At page 837, 1st paragraph, it teaches direct topical application of diluted bupivacaine instilled into the pelvic peritoneal cavity *before* the closure of the umbilical port in the procedure (Office Action, at page 4) (emphasis added).

Applicant, respectfully, does not agree with this rejection and asserts, for the reasons provided below, that pending claims 1-4 and 10 are not anticipated by Kelly.

Anticipation under 35 U.S.C. § 102 requires that every element and limitation of a claimed invention must be found within a single prior art reference; moreover, each of the elements disclosed in that reference must be arranged as they are in the claim (*see e.g. Karsten Mfg. Corp. v. Cleveland Golf Co.* 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001); *Brown v. 3M* 242 F.3d 1349, 1351 (Fed. Cir. 2001); *Perkin-Elmer Corporation v Computervision Corporation* 732 F.2d 888, 894 (Fed. Cir. 1984). The disclosure of the cited reference must provide enough detail and sufficient clarity that one of ordinary skill in the art would have recognized the claimed subject matter existed (*see e.g. ATD Corp. v. Lydall, Inc.* 159 F.3d 534, 545 (Fed. Cir. 1998)); that is "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention (*Scripps Clinic & Research Fdn. v. Genentech, Inc.* 927 F.2d 1565, 1576 (Fed. Cir. 1991)).

Moreover, an allegation of inherent anticipation must be based upon objective fact and scientific reasoning that demonstrate that the “allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art” (emphasis in the original; citations omitted). (*Ex parte Levy* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Interf., 1990)). In addition the cited reference must disclose each and every limitation of the claimed invention and the location and the location of each element of that disclosure must be identified as well (*Id.* at 1462). Finally, inherency cannot be based on probabilities or possibilities; the “mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” (*Continental Can Co. USA v. Monsanto Co.* 948 F.2d 1264, 1269 (Fed. Cir. 1991)).

Independent claim 1 of the present application is directed toward a method of preventing or ameliorating pain arising from a surgically closed wound by application of the recited drug formulation on or adjacent to an exterior surface of the wound (*i.e.* the surgically-closed wound). That is, the presently-claimed methods are directed toward a method of preventing or ameliorating pain *after* the wound has been closed surgically.

In contrast to the present invention, Kelly teaches intra-abdominal administration of bupivacaine though an open wound (*i.e.* through the open “umbilical port”) to the interior surfaces of the body (*i.e.* “into the pelvic peritoneal cavity” page 837, left col., second paragraph) before closure of umbilical port. Kelly, does not teach, or even suggest, administration of bupivacaine on or adjacent to an exterior surface after the wound has been closed. Those of ordinary skill in the art would infer from the teaching of Kelly that an intact (*e.g.* surgically-closed) skin surface would prevent effective anesthesia of pain arising from the laparoscopic sterilization procedure described.

Since administration of the recited drug formulation to an exterior surface of a surgically closed wound are recited elements of pending independent claim 1, Applicant respectfully submits that Kelly does not disclose each and every element and limitation of the presently-claimed method of independent claim 1. Consequently, Kelly cannot be construed as anticipating the presently-claimed invention. Accordingly, Applicant respectfully requests that the rejection of independent claim 1, and claims 2-4 and 10 dependent thereon, as anticipated under 35 U.S.C. § 102 over Kelly, be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 102 OR § 103
OVER ZHANG SHOULD BE WITHDRAWN

Claims 1-25 are rejected under 35 U.S.C. § 102, as allegedly anticipated by U.S. Patent No. 6,528,086 to Zhang (hereafter “Zhang”), or alternatively, claims 1-25 are rejected under 35 U.S.C. § 103, as allegedly obvious over Zhang, for the reasons provided at page 5 of the Office Action. In particular, it appears that the Examiner has alleged that Zhang, at column 2, lines 19-22, discloses treatment of surgically-closed wounds (as recited in pending independent claims 1 and 25), and that Zhang, at column 13, lines 20-28 and at column 14, lines 65-67, discloses the use of a patch. Applicant, respectfully, does not agree with this rejection.

The legal standard for anticipation under 35 U.S.C. § 102 is provided above.

The legal standard for establishing *prima facie* obviousness requires that three criteria be met: (1) the prior art, either alone or combination, must teach or suggest each and every limitation; (2) a suggestion or motivation in the cited references or in the art to modify or combine the cited references; and (3) the cited references must provide a reasonable expectation of successfully achieving the claimed invention. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); *In re Wilson*, 165 U.S.P.Q. 494, 496 (CCPA 1970).

Thus, the mere listing of elements or attributes of elements that may be discovered or alleged in the prior art, without more, simply amounts to “hindsight reconstruction...using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.” (*Grain Processing v. American Maize-Products* 5 USPQ2d 1788, 1792 (Fed. Cir. 1992) (citation and internal quotation omitted).

For the reasons provided below, Applicant respectfully submits that neither of these legal standards are met by Zhang. Applicant respectfully submits that Zhang does not disclose each and every element and limitation of either of the pending independent claims, *i.e.* claims 1 and 25. Moreover, Applicant respectfully submits that *prima facie* obviousness has not been

established since the three criteria noted above are not met. More specifically, Applicant respectfully submits that Zhang does not teach or suggest the claimed method, as recited in independent claim 1, for preventing or ameliorating the pain of a surgically-closed wound, much less a patch comprising an amount local anesthetic that would be therapeutically-effective for preventing or ameliorating the pain of a surgically-closed wound.

The Examiner has directed Applicant's attention to column 2, lines 19-22, of Zhang regarding closed wounds. In response Applicant notes that a more complete review of this section of Zhang (col. 2, lines 12-37) informs us that Zhang is addressing anesthesia required before and during specified medical procedures. For example anesthesia would be required for debridement of burned tissues, as well as for cleansing or closing of ulcers. However, this section clearly neither teaches nor suggests application of anesthesia *after* the wound has been closed.

Applicant therefore respectfully submits that this section of Zhang only makes the observation that patients with open wounds may experience pain requiring treatment. Zhang does not contemplate pain arising from a surgically-closed wound. Applicant further submits that Zhang cannot be construed as disclosing or even suggesting preventing or ameliorating the pain of a surgically-closed wound; *i.e. after* the wound has been closed.

Thus, Applicant respectfully submits, Zhang does not disclose prevention or amelioration of the pain arising from a surgically-closed wound, as recited in pending independent claim 1. Therefore, Applicant respectfully submits that since Zhang does not disclose each and every element and limitation of the presently-claimed method of independent claim 1, Zhang cannot be construed as anticipating the presently-claimed invention of independent claim 1. Accordingly, Applicant respectfully requests that the rejection of independent claim 1, and claims 2-24, dependent thereon, as anticipated under 35 U.S.C. § 102 over Zhang, be withdrawn.

As noted above, *prima facie* obviousness requires that the cited art much teach or suggest each and every limitation of the claimed invention. Again, Zhang neither discloses nor fairly suggests prevention or amelioration of pain arising from a surgically-closed wound, as recited pending independent claim 1. Moreover, no basis has been provided for modifying the disclosure of Zhang in an attempt to arrive at the present invention. Accordingly, the criteria required for establishing *prima facie* obviousness have not been met, and, therefore, it follows

that the presently claimed method of claim 1 cannot be construed as obvious under 35 U.S.C. § 103 over Zhang. Accordingly, Applicant respectfully requests that the rejection of independent claim 1, and claims 2-24, dependent thereon,¹ as obvious under 35 U.S.C. § 103 over Zhang, be withdrawn.

Similarly, although the Examiner has directed Applicant's attention to column 13, lines 20-28 and column 14, lines 65-67 of Zhang as allegedly disclosing the use of a patch, Applicant respectfully submits that Zhang does not teach or suggest Applicant's patch, as recited in independent claim 25. The alleged invention of Zhang is directed toward fluid compositions that can be applied to a surface and then converted to an essentially-solid material that, subsequently, can be easily removed (*see e.g.* Zhang column 13, lines 21-39).

Moreover, Zhang clearly and deliberately distinguishes his alleged invention from, *inter alia*, a "drug formulation patch" (Zhang, at column 14, line 61, through column 15, line 28). According to Zhang the alleged *disadvantages* of a patch comprising a therapeutic agent (*i.e.* as recited in pending claim 25) *are overcome by his alleged invention* (*see e.g.* column 14, line 64 through column 15, line 28). For example, Zhang discloses application of a therapeutic agent within a cream that is later solidified by contact with a gauze dressing saturated with an agent (*e.g.* borate) that diffuses into the applied cream and converts it into an easily-removed solid (Zhang, at column 13, lines 21-39). That is, in direct contrast to the presently-claimed patch of independent claim 25, the applied gauze or other "patch" of Zhang does not comprise a therapeutic agent; rather it comprises a cross-linking agent that can diffuse into a surface-applied fluid and convert it to an easily-removed solid (Zhang, at column 13, lines 21-39 and column 15, lines 6-28).

Thus, Applicant respectfully submits, Zhang does not disclose or even suggest a patch comprising a local anesthetic. In fact, as noted above, to the extent that Zhang can be construed as disclosing a "patch," that patch, clearly, unambiguously, and deliberately does not comprise any therapeutic agent, much less the presently-recited amount therapeutically effective to prevent or ameliorate pain from a surgically-closed wound. This conclusion is reinforced by the observation, noted above, that Zhang does not disclose or even suggest treatment of pain arising

¹ "Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious (*In re Fine* 837 F.2d 1071, 1076 (Fed. Cir. 1988)).

from a surgically-closed wound. Therefore, Applicant respectfully submits that since Zhang does not disclose each and every element and limitation of the presently-claimed method of independent claim 25, Zhang cannot be construed as anticipating the presently-claimed patch of independent claim 25. Accordingly, Applicant respectfully requests that the rejection of independent 25, as anticipated under 35 U.S.C. § 102 over Zhang, be withdrawn.

As noted above, *prima facie* obviousness requires that the cited art much teach or suggest each and every limitation of the claimed invention. Again, Zhang neither discloses nor fairly suggests a patch comprising any therapeutic agent, much less a patch comprising a local anesthetic in the presently-recited amount that is therapeutically effective to prevent or ameliorate pain from a surgically-closed wound, as recited pending independent claim 25. Moreover, no basis has been provided for modifying the disclosure of Zhang in an attempt to arrive at the present invention of claim 25. Therefore, the criteria required for establishing *prima facie* obviousness have not been met, and, therefore, it follows that the presently-claimed patch of claim 25 cannot be construed as obvious under 35 U.S.C. § 103 over Zhang. Accordingly, Applicant respectfully requests that the rejection of independent claim 25 as obvious under 35 U.S.C. § 103 over Zhang, be withdrawn.

In summary, Applicant respectfully submits that, for all the reasons provided above, the rejection of pending claims 1-4 and 10 over Kelly and the rejection of pending claims 1-25 over Zhang have been overcome. Accordingly, Applicant respectfully requests that the rejection of claims 1-4 and 10, as anticipated under 35 U.S.C. § 102, and the rejection of claims 1-25 as anticipated under 35 U.S.C. § 102 or as obvious under 35 U.S.C. § 103 over Zhang, be withdrawn.

CONCLUSION

Applicant believes that each ground for rejection of the pending claims has been successfully overcome or obviated. Accordingly, Applicant respectfully requests that the rejection of claims 1-25 the rejection of claims 1-25 under 35 U.S.C. § 102 or 35 U.S.C. § 103 over Zhang, and the rejection of claims 1-4 and 10 under 35 U.S.C. § 102 over Kelly, be withdrawn. Applicant submits that the entire application is now in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Applicants do not believe that a fee is due for this submission, other than the fees due for an extension of time and for the submission of a Request for Continued Examination. However, should a fee be due, please charge the required amount to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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Samuel B. Abrams 30,605
Samuel B. Abrams (Reg. No.)

By: Michael J. Ryan 41,283
Michael J. Ryan (Reg. No.)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939